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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,982	05/31/2005	Shlomo Lewkowicz	P-4433-US	6340
49443 7590 10/28/2009 Pearl Cohen Zedek Latzer, LLP 1500 Broadway 12th Floor New York, NY 10036				
EXAMINER				
LAMPRECHT, JOEL				
ART UNIT		PAPER NUMBER		
3737				
MAIL DATE		DELIVERY MODE		
10/28/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/536,982

**Applicant(s)**

LEWKOWICZ ET AL.

**Examiner**

JOEL M. LAMPRECHT

**Art Unit**

3737

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24, 27, 29-31, 35, 36 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24, 27, 29-31, 35, 36 and 38-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/6/09

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/09 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **24, 27, 29-31, 35, 36, 38, 39, and 42-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Luiken (US 2001/0055566 A1) in view of Alfano et al (US 6,240,312 B1). Luiken discloses tumor screening related methods including administration of fluorescent dye and irradiation with visible and fluorescent (excitation) radiation to produce images captured on an image sensor (0004-0007) for the purpose of diagnosing cancerous tissues. The light excitations including both monochromatic light, polychromatic light, and combinations of flashing sequences (Including use of a circa 1987 technique for White light/fluorescent light excitation) (0009, 0018-0024), the incorporation of black-light or Woods lamps for dark periods of capture (0021), the acquisition of real images and fluoroscopic images during different time periods (0018-0028, 0030, and including at least one fluorescent compound with illumination ranges outside the visible spectrum (Table 1)), washing of excess dye before image-capturing (0029), and administrations of antibodies associated with GI cancer including CEA (0034-0038). Luiken does not disclose the use of an ingestible imaging capsule; rather focuses on methods involving endoscopes of certain capabilities and other techniques rather than the specific properties of the endoscopes or other imagers used. Attention is then directed to the secondary reference by Alfano et al which discloses an ingestible internal device for wireless capturing and imaging (including storage of images captured) of the GI tract (Col 2 Line 10-65) to enable cancer diagnosis and treatment (Col 3 Line 65- Col 4 Line 59). The methods of Alfano et al include the use of flash illumination capture (Col 6 Line 20-50) and wavelength selection filters in the non-visible light spectrum (claim 6). It would have been obvious to one of ordinary skill in the art at

the time of the invention to have utilized the methods of wireless transmission and endoscopy of Alfano et al with those methods of Luiken for the staining and diagnostic imaging of tissues to enable portable diagnosis of cancer and other diseases with micro-scale technology and onboard storage/transmission.

Claims **40 and 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Luiken (US 2001/0055566 A1) in view of Alfano et al (US 6,240,312 B1) as applied to claim 24 above and in further view of Akashi et al (novel Gastric Cancer Associated Mucin Antigen Defined By A3D4). Luiken in view of Alfano et al discloses all that is listed above but fails to disclose the use of an antigenic determinant such as Gastric Mucin for diagnosis. Attention is then directed to the secondary reference by Akashi et al which discloses such a determinant for the purpose of diagnosing gastric cancer. It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized this Mucin determinant as disclosed by Akashi et al with the methods of Luiken in view of Alfano et al to correctly diagnose cancerous tissues in the GI tract.

### ***Response to Arguments***

Applicant's arguments filed have been fully considered but they are not persuasive. Regarding the argument that Luiken does not teach obtaining a white light/fluorescent image of the GI tract, Luiken specifically notes a method for such a procedure in [0009] which includes flashing white and fluorescent light in sequence to acquire multiple images for cancer diagnosis. The new claims require a comparison for

diagnosis, and the acquisition of diagnostic information, both features which are inherent to a medical imaging procedure.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/  
Supervisory Patent Examiner, Art  
Unit 3737

JML